UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte KENNETH F. BUECHLER, and
PAUL H. MCPHERSON

Appeal No. 2004-2387
Application No. 09/349,194

ON BRIEF

Before MILLS, GRIMES, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

An oral hearing in this case was scheduled for January 13, 2005. Upon reviewing the case, however, we have determined that an oral hearing will not be necessary and we render the following decision based on the record. See 37 CFR § 41.47(f). Note that this appeal is related to Appeal No. 2004-2149, Application Serial No. 09/687,051, and is decided concurrently therewith.

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 85-96, 102-106 and 114-133. Claim 85 is representative of the subject matter on appeal, and reads as follows:

> 85. An assay for determining the presence or amount of a free and complexed cardiac specific isoform of troponin in a patient sample, said assay comprising:
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> performing an immunoassay with an antibody which specifically binds said free cardiac specific isoform of troponin, and which specifically binds said cardiac specific isoform of troponin in a binary complex comprising one other troponin component selected from the group consisting of troponin I, troponin C and troponin T, and which specifically binds said cardiac specific isoform of troponin in a ternary complex comprising two other troponin components selected from the group consisting of troponin I, troponin C and troponin T; and
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> detecting a signal from said immunoassay resulting from said antibody binding said free and complexed cardiac specific isoform of troponin, wherein said signal is at least a factor of two larger than a signal resulting from said antibody binding to an equal number of (i) free troponin components which are not said cardiac specific isoform of troponin; (ii) troponin complexes which do not comprise said cardiac specific isoform of troponin; or (iii) a combination of (i) and (ii), and wherein said signal is related to the presence or amount of said free and complexed cardiac specific isoform of troponin in said sample.

No prior art is relied upon by the examiner in the rejection of the claims on appeal.

Claims 85-96, 102-106 and 114-133, all of the claims on appeal, stand rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the specification fails to enable the full scope of the claimed invention. After careful review of the record and consideration of the issues before us, we reverse.

DISCUSSION

Claims 85-96, 102-106 and 114-133 stand rejected under 35 U.S.C. § 112, first paragraph, on the grounds that

> the specification, while being enabl[ing] for an assay for determining free and complexed cardiac specific isoforms of troponin (cTn) using a cocktail of antibodies, each having specific binding for free cTnI, binary complex of cTn, and ternary complex of cTn, does not reasonably provide enablment for an assay for determining free and complexed cTn using an antibody, i.e. single antibody, having specific binding for each and all of free cTnI, binary complex of cTn, and ternary complex of cTn. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claims.

Examiner's Answer, pages 3-4.

The rejection then looks at each of the Wands factors. See In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1403 (Fed. Cir. 1988). The factors discussed by the court in Wands include: (1) the quantity of experimentation necessary to practice the invention, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

As to the nature of the invention, the examiner asserts that "the invention is directed to a method for determining the presence or amount of each and all free and complexed isoforms of cTn using a cocktail of antibodies having specific binding for each and all of free, binary complex, and ternary complex isoforms of

cTn." Examiner's Answer, page 4. As to the state of the prior art, the examiner contends that the prior art "fails to disclose a method for determining the presence or amount of all free, binary and ternary complexed isoforms of cTn using an antibody having specific binding for each and all of the free, binary, and ternary complexed isoforms of cTn." Id.

With respect to the predictability or lack thereof in the art, the rejection focuses on the specification, stating that "there is no predictability based on the instant specification that the presence or amount of all of the free, binary and ternary complexed isoforms of cTn in a sample can be determined using an antibody wherein the antibody has specific binding for each and all of the free, binary, and ternary complexed isoforms of cTn." Id. at 5. As to the amount of direction or guidance present, and the presence or absence of working examples, the rejection focuses on the lack of a working example using an antibody that specifically binds each of the free, binary and ternary complexed forms of cTn. See id. The rejection acknowledges that the level of skill in the art is high, but asserts that it would require an undue amount of experimentation to make and use the method as claimed. See id.

Finally, the rejection focuses on the breadth of the claims. The rejection acknowledges that

> [a]t pages 21-22, the specification shows how to generate and select antibodies that are sensitive[1] or insensitive[2] to the binding of

[1] The specification defines a sensitive antibody as an antibody that will tend to bind only a single form of troponin. See Specification, page 6.

> free troponin I or T, troponin I or T in binary complexes, and troponin I or T in ternary I/T/C complexes; this is accomplished by purification of free troponin I or T, binary troponin I/T, T/C, and I/C complexes and ternary I/T/C complexes, respectively, then injection into mice or rabbits to generate monoclonal or polyclonal antibodies. The antibodies are then screened for affinity and specificity with the purified free troponin, binary complexes of troponin, and ternary complexes of troponin.

Id. at 6-7.

The rejection then goes on to argue, however, that the specification only exemplifies the use of a cocktail of antibodies that can bind to free cTn, binary complexed cTn and ternary complexed cTn, and does not provide a working example using an antibody that can bind to all of the forms of cTn. The rejection asserts that "[t]he fact insensitive antibodies that bind more than one form of cTn has been characterized, is not sufficient to enable the breadth of the claimed method to use a single insensitive antibody in an assay to determine the presence or amount of all free cTn, binary complexed cTn, and ternary complexed cTn." Id. at 7.

Appellants argue that the rejection is based upon the "unsupported assertion that, while the specification is enabling with regard to a pool of antibodies that specifically bind to each form of a cardiac specific troponin isoform (i.e., free isoform, the isoform in binary complexes comprising another troponin component, and the isoform in ternary complexes comprising two

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[2] The specification defines an insensitive antibody as an antibody that will tend to bind more than one form of troponin, i.e., oxidized and reduced forms of the troponin, or free or complexed forms of troponin. See Specification, page 6.

additional troponin components), the specification is not enabling with regard to a single antibody that binds to each of the recited troponin forms." (Appeal Brief, page 12 (emphasis in original). We agree.

"[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971) (emphasis in original). "[It] is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement." Id. at 224, 169 USPQ at 370. Here, the examiner has not provided "acceptable evidence or reasoning which is inconsistent" with the specification, and therefore has not met the initial burden of showing nonenablement.

The rejection is primarily premised on the fact that the specification fails to provide a working example of an assay for determining free and complexed cTn using a single antibody that specifically binds to each and all of the free, binary complexed and ternary complexed cTn. The rejection, however, provides no evidence to support the assertion that it would require an undue amount of

experimentation to generate and screen for antibodies that can bind to the free and binary and ternary complexed forms of cTn, and the rejection is reversed.

As acknowledged by the rejection, the specification shows how to generate and select antibodies that are sensitive or insensitive to the binding of free troponin I or T, troponin I or T in binary complexes, and troponin I or T in ternary I/T/C complexes. See Examiner's Answer, page 7; see also, Specification, pages 21-24. Moreover, as noted by appellants, the specification states that while the immunoassay may be formulated using a cocktail of antibodies, it may also be formulated "with specific antibodies that recognize epitopes of the troponin I and T in the complexes and also the unbound troponin I and T." Specification, page 24. Example 23 of the specification demonstrates the selection of an antibody that binds to both free troponin I and troponin I in a ternary complex. See id. at 88.

The specification thus teaches the skilled artisan how to generate and screen for antibodies having the desired binding specificity. The fact that appellants failed to provide a working example of an antibody that binds to free cTn, as well as binary and ternary complexed cTn is not in and of itself dispositive on the issue of whether the specification enables such an antibody given the lack of evidence on the part of the rejection demonstrating why one skilled in the art would not expect to be able to produce such an antibody.

OTHER ISSUES

We note that appellants submitted an article of Giuliani et al., "Determination of Cardiac Troponin I Forms in the Blood of Patients with Acute Myocardial Infarction and Patients Receiving Crystalloid or Cold Blood Cardioplegia," Clinical Chemistry, Vol. 45, pp. 213-222 (1999), to support their position that "[a] method of making even a single monoclonal antibody that binds to all forms (free, binary and ternary of cTnI) is feasible without undue experimentation." Communication to the Examiner dated September 25, 2003, page 3. Our review of the record however, does not reveal whether the examiner ever considered the article, and it is thus unclear if the article is part of the record on appeal. In view of our disposition of the appeal, we see no need to remand the application at this time for clarification, but the examiner should in the future clearly indicate on the record whether such evidence has been considered and made of record.

CONCLUSION

Because the rejection under 35 U.S.C. § 112, first paragraph, on the grounds that the specification fails to enable the full scope of the claimed subject matter, fails to provide acceptable evidence or reasoning that is inconsistent with

the specification, and thus fails to meet the initial burden of showing nonenablement. Therefore, the rejection is reversed.

REVERSED

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